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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,262	07/03/2003	Eli Gilboa	1430/13	3315

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/613,262

Applicant(s)

GILBOA ET AL.

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 13 and 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's response to the restriction requirement received on 4/27/06 has been entered. Applicant's election of the invention of group VI and the species VEGF for examination is acknowledged. Upon further consideration, however, the examiner has decided to rejoin the inventions of groups V-VIII. As the applicant did not indicate that the election was with traverse or provide any arguments traversing the grounds for restriction/election, applicant's election is considered to have been made without traverse, and the restriction requirement is made FINAL.

Claims 1-18 are pending in the instant application. Claims 1-9, and 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/27/06. Claims 10-15 are therefore currently under examination. An action on the merits follows.

### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 12/8/03 and 11/21/05 have been considered.

The listing of references in the specification, see in particular pages 28-35, is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper."

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Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Drawings***

The drawings are objected to because Figure 4 does not correspond to the brief description of the figure in the specification. Figure 4 shows 12 completely black boxes. The brief description of Figure 4 does not clarify what is supposed to be seen in this figure as it simply states that the figure illustrates the inhibition of angiogenesis in mice immunized with angiogenesis-associated products. However, as noted, since the boxes under the headings of VEGF, VEGFR-2, and PBS are all completely black, no inhibition is shown. Please note that the drawings available to the examiner are scanned copies or the originals submitted by applicant. Any corrected drawing sheet submitted by applicant should be of such quality that images present in the figures will be legible following scanning.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

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renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/45018 (September 10, 1999), hereafter referred to as Hicklin et al. The applicant claims a composition for treating cancer comprising antigen presenting cells presenting at least one angiogenesis-related antigen, wherein the antigen is VEGF, and the antigen presenting cells are dendritic cells.

Hicklin et al. teaches dendritic cells which have been pulsed with an angiogenesis-related antigen or transfected with a nucleic acid encoding an angiogenesis-related antigen, and the use of the cells to treat tumors through inhibition of tumor angiogenesis (Hicklin et al., pages, 1, 16-17, and 21-25, especially claims 1-2, 17-18, and 23). Specifically, Hicklin teaches antigen presenting cells that are dendritic cells, and an angiogenesis related antigen that is VEGF

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(Hicklin et al., pages 17 and 21, and page 8). Thus, by teaching all the limitations of the claims as written, Hicklin et al. anticipates the instant invention as claimed.

Claims 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,853,719 (December 29, 1998), hereafter referred to as Nair et al. , as evidenced by Heer et al. (2001), Clin. Can. Res., Vol. 7, 3491-3494. The applicant claims a composition for treating cancer comprising antigen presenting cells presenting at least one angiogenesis-related antigen and at least one tumor antigen, wherein the angiogenesis related antigen is VEGF, the antigen presenting cells are dendritic cells, and wherein the cells are transfected with mRNA encoding VEGF and the tumor antigen.

Nair et al. teaches antigen presenting cells, specifically dendritic cells, transfected with RNA derived from tumors useful for the treatment of cancer (Nair et al., columns 1-3, and 12-14, in particular claim 10). Nair et al. further teaches that the RNA is poly A+ RNA, also known as mRNA, that the RNA derived from the tumor comprises tumor related and tumor specific RNA (Nair et al., columns 1, 3, and 5). In addition, Nair et al. teaches that the RNA is derived from a breast cancer tumor (Nair et al., columns 2, 12, 14, and claim 13). Nair et al. also states that since unfractionated total poly A+ RNA derived from the tumor is used, it is not necessary the specific tumor antigens be identified (Nair et al., column 3, lines 29-32) It is also noted that Nair et al. teaches that tumor specific antigens include RNA present in the tumor cells that is not present in a normal cell, and RNA present at a higher level in a tumor cell than in a normal cell (Nair et al., column 3).

Although Nair et al. does not identify mRNA encoding specific tumor antigens or other antigens present in poly A+ RNA prepared from breast cancer tumor cells, breast cancer tumor cells inherently comprise mRNA encoding the tumor antigen CEA and further comprise mRNA encoding for the angiogenesis related antigen VEGF. This is evidenced by Heer et al., who teaches that breast cancer cells produce significant amounts of VEGF and further express the tumor antigen CEA (Heer et al., pages 3491 and 3493). Thus, any preparation of poly A+ RNA prepared from a breast cancer tumor cell would comprise mRNA encoding both VEGF and CEA, and a cell prepared using total poly A+ RNA from a breast cancer cell, as taught by Nair et al., would therefore inherently comprises mRNA encoding VEGF and CEA.

As such, by teaching an antigen presenting cell, and particularly a dendritic cell, transfected with total poly A+ RNA from a breast cancer cell, Nair et al. anticipates the instant invention as claimed.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

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The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

**ANNE M. WEHBE' PH.D**  
**PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'Anne M. Wehbe', with a long horizontal stroke extending to the right.